DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Atlanta District Office

60 8th Street, N.E.
Atlanta, Georgia 30309

January 5, 1999

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Kevin Phillips
President/Chief Executive Officer
Clinical Diagnostics, Inc.
2606 Eden Terrace
Rock Hill, South Carolina 29730

WARNING LETTER

Dear Mr. Phillips:

An inspection of your firm was conducted on November 10-16, 1998. Our investigator found that you are distributing a Blood Glucose Monitoring System. The glucose test strips and control solution components are manufactured at your Rock Hill location. This monitoring system is a device as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The investigator documented several significant deviations from the Quality System Regulation as set forth in Title 21 of the Code of Federal Regulations (21 CFR), Part 820. These deviations cause the devices you manufacture and distribute to be adulterated within the meaning of Section 501(h) of the Act.

You have failed to establish and maintain a quality system appropriate for the medical devices that you manufacture. Management with executive responsibility had not established a policy and objectives for, and commitment to, quality. A management representative had not been identified to ensure that the quality policy was understood, implemented, and maintained at all levels of your organization. You have not established a quality plan which defines the quality practices, resources, and activities relevant to your devices. You have failed to establish procedures for quality audits and to conduct such audits to determine if the quality system is in compliance with the requirements and to determine the effectiveness of the quality system. Although you have been manufacturing devices since 1994, no audit was initiated until August of 1998.

You have failed to appropriately validate manufacturing processes currently utilized for the glucose solution, glucose wipes strips, and control solution. You could not provide documented

evidence which established a high degree of assurance that the manufacturing processes were effective and could consistently produce a product meeting its predetermined specifications and quality attributes. You have not established if the various settings which are currently monitored, such as temperature, pressure, line speed, and other production parameters, are appropriate.

You failed to establish and maintain complaint procedures which would assure the appropriate review and processing of complaints in a uniform and timely manner. Your complaint records were disorganized and failed to include all relevant information. Although required by your firm's written procedures, quality assurance was not involved in the determination of the need for an investigation or if corrective action was required for complaints. For 103 out of [redacted] complaints, the Customer Service department merely replaced deficient products and then closed the complaints. None of these complaints included a review or evaluation by the quality assurance department. Of the twenty five (25) complaints reviewed in detail during the inspection, none contained any documented follow-up or failure investigation as required. Our investigator found no evidence in any complaint documentation reviewed to indicate that your firm had evaluated any reported quality problem associated with the devices you manufacture and distribute.

You have failed to establish and maintain procedures for finished device acceptance to ensure that each device meets acceptance criteria. You had failed to establish procedures for the receipt, in-process testing, and final testing of the [redacted] meters. Review of inspection reports indicated distribution of meters which failed specifications, were subjected to incomplete inspections, and were not reviewed by quality assurance prior to release. The device history records were also very disorganized and some of the records requested could not be located. In several instances it was difficult to determine what method was used during inspectional testing.

You have failed to establish formal procedures for the release of production lots of glucose test strips to include coding, regression analysis, and data interpretation of the control solution assigned values. Several performance tests are conducted to determine the accuracy of these strips. None of these processes have been validated by your firm.

You have failed to establish and maintain procedures for implementing corrective and preventive action. There were no controls in place to identify, correct or prevent recurrence of quality problems. The failure to involve management in quality issues, the lack of involvement by quality assurance in the complaint review process, and the absence of quality audits makes the identification and prevention of nonconformities and quality problems much more difficult at your firm.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. At the close of the inspection, the Inspectional Observations (FDA 483) was issued to and discussed with Mr. Byron McLean, Division Controller. A copy of the FDA 483 is enclosed for your review. The specific violations noted in this letter and in the FDA 483 could be symptomatic of serious underlying problems in your firm's quality assurance systems. You are responsible for

investigating and determining the causes of the violations identified by the FDA. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Also, no request for Certificates For Products for Export will be approved until the violations related to the subject devices have been corrected.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory actions being initiated by the FDA without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office in writing within fifteen (15) days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to assure that similar violations will not recur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

We are in receipt of the December 8, 1998, response from your firm to the FDA 483. Portions of the response such as those addressing the validation and complaint handling concerns, appear to be satisfactory. These corrections need to be verified during our next inspection however. We still have significant concerns over other portions of this response, such as those involving quality auditing, quality policy, approval of suppliers, corrective action plans, and establishing written procedures. A more detailed review of your response will be forwarded in another letter. We also acknowledge that you had taken steps to address some of these deficiencies prior to our inspection, such as the hiring of an outside consultant. Although this is a "clear and substantial commitment to comply with FDA regulations" as you assert in your response, your firm has been manufacturing medical devices since 1994. This would appear to have been sufficient time to implement an effective quality system already.

You may reference the December 8 letter in your Warning Letter response, if you feel that it adequately addresses any of the issues raised in this letter. Your response should be sent to Philip S. Campbell, Compliance Officer, at the address noted in the letterhead.

Sincerely yours,

for Roger E Kline

Ballard H. Graham, Director
Atlanta District

Enclosure